Remarks

In this paper, claim 1 is amended, as is the specification. Claims 1-7 are pending. Reconsideration of the claims, as amended, is requested.

Priority Document

The Office Action indicates that the certified copy of the priority document has not been received. Applicant submitted the copy on June 29, 2004. The PTO Private PAIR system shows the document as having been received and processed. A copy printed from PAIR is enclosed with the paper.

Specification

The specification has been amended as suggested to provide appropriate headings for various sections of the specification.

The Invention, in General

The invention of the pending application relates to an inhalation therapy device that includes an oscillatable membrane for nebulising a liquid supplied to one side of the membrane. When the membrane oscillates, the liquid is nebulised through the membrane and delivered on the other side of the membrane as an aerosol. To cause oscillation of the membrane, the inhalation therapy device has an oscillation generating device having at least one connecting means for receiving an oscillating control signal. The device also includes a control means for supplying the oscillation control signal to the connecting means so that the oscillation generating device causes the membrane to oscillate.

The above summary describes the basic elements of the inhalation therapy device. The device delivers a very precise dose of the medicament to be inhaled by the patient. Applicant acknowledges that the known core elements of such an inhalation therapy device are the membrane, oscillation generating device, and the control means. One having average skill in the art of inhalation therapy devices avoids any technical deviations. When designing the construction and control of the core elements, the

average skilled person focuses on the generation of the aerosol and optimizes the core elements.

The invention of the pending application adds a further element to the core elements, the new element being unrelated to aerosol generation. According to the present invention, the control means is designed such that a further control signal is supplied to the oscillating generating device, causing the membrane to oscillate in an audible frequency range, thus emitting an audible signal for a user. As such, the membrane is used for an additional purpose, namely to emit an audible signal for the user, the additional function having no influence of the nebulising performance. This additional function is achieved by providing an additional signal in parallel with the major signal causing the oscillation. The membrane is used both as an aerosol generator for nebulising the liquid and as a signal generator for the user. See also paragraphs [0005] and [0006] of the specification.

Claim 1 has been amended in this paper to better define the inhalation therapy device. Pending claim 1 recites that the device has a control means that indirectly causes the membrane to oscillate, and that the control means also causes the membrane to oscillate in the audible frequency range so as to emit an audible signal for a user.

Applicant notes that claim 1 has been amended to replace the term "supply" with "receive" (i.e., "at least one connecting means for supplying an oscillation control signal" has been amended to be "at least one connecting means for receiving an oscillation control signal", and "when the oscillation control signal is supplied such that..." has been amended to be "when the oscillation control signal is received such that..."). Paragraphs [0004] and [0007] have likewise been amended, to change "supply" to "receive". When taken in context of the complete paragraph, support for these changes is evident.

Claim Rejections

Claims 1-5 were rejected under 35 U.S.C. 102(b) as anticipated by Robertson et al. (U.S. Patent No. 5,487,378). Claims 6 and 7 were rejected under 35 U.S.C. 103(a) as unpatentable over Robertson et al. Applicant disagrees with both of these rejections.

Robertson et al. does not disclose, teach or suggest a device as recited by the pending claims, nor would one skilled in the art be lead to the device of the pending claims.

The nebulizer of Robertson et al. includes a vibrator element 54 which causes ultrasonic vibrations within a liquid, such that the ultrasonic vibrations propagate to a membrane 50, which then nebulises the liquid which in turn is delivered as an aerosol 72. Column 10, lines 37-43 of Robertson et al. describe that "a vibrator element (54) ... is attached to the disc (52) around the mounting rim (68) by adhesive or bonding techniques. The vibrator element (54) comprises a brass disc electrode (53) about 0.2 m *[sic]* thick and 20 mm diameter onto which is bonded a smaller disc of piezo-electric material (56)." Electrodes are attached to the vibrator element so that a control signal can be supplied. The generation f the aerosol is described at column 10, lines 56-64 as follows:

> When the vibrator element (54) is excited into a suitable resonance then ultrasonic vibrations are transferred into the liquid (16) and around the rim of the vibrator element into the disc (52) by motion of the vibrator element (54). These effects result in ultrasonic pressure pulses within the liquid (16) behind the nozzle array (50) and droplets (72) are formed as the liquid (16) is periodically ejected through the nozzle array (50) at ultrasonic frequencies.

It is clear from these passages that the aerosol is generated due to the ultrasonic pressure pulses caused by the vibrator in the liquid. The pressure pulses reach the nozzle array, droplets are formed and ejected through the nozzle array at ultrasonic frequencies. Obviously, Robertson et al. not disclose a vibrator element that causes the membrane to oscillate in a manner so that a liquid disposed on one side of the membrane is nebulised through the membrane. The device of Robertson et al. relies on the ultrasonic pressure pulses within the liquid reaching the nozzle array to nebulise the liquid.

The Office Action points to column 2, lines 36-40 for the teaching of vibrating a membrane to form and dispense droplets of liquid through the membrane. This passage pointed to is in the Background section of Robertson et al. Applicant does not dispute

that prior devices use core elements such as a membrane, oscillation generating device, and control means. As described in the section titled The Invention, in General, one having average skill in the art of inhalation therapy devices avoids any technical deviations from these core elements. Robertson et al. did deviate, however, from the core elements, in that the oscillation generating device of Robertson et al. does not oscillate the membrane.

The pending claims include a further element to the core elements, the new element being unrelated to aerosol generation, being the oscillation of the membrane to emit an auditory signal.

Applicant acknowledges that Robertson et al. teaches the generation of an audible signal, for example, as indicated by block 160 of FIG. 10. However, as explained by the text at column 14, lines 29-34, it is the vibrator element 54 that generates the audible signal, not the membrane as is recited by the pending claims.

> If however, the 'contemplated dose' signal is not received before the cycle time (176) times out then the control logic (162) generates an alarm signal indicating a failed dose delivery. This alarm signal activates an audio or visual alarm (160). One such possible audible alarm is to drive the vibrator element (54) with an audio frequency. [Col. 14, l. 29-34].

This understanding, that the vibrator element generates the audible signal rather than the membrane, is in line with other passages of Robertson et al., such as at column 11, lines 41-60, where it mentioned that the vibrator element 54 is an audio sounder.

Applicant asserts that it is incorrect to state that FIG. 10 of Robertson et al. and the corresponding text teaches that the membrane 50 is caused to oscillate in the audible frequency range and thus emit an audible signal. Using the membrane for emitting an audible signal is not even remotely contemplated by Robertson et al., since it is emphasized by Robertson et al. that the vibrator element is the audio sounder.

Applicant contends that at least for these reasons, the pending claims are neither anticipated by nor obvious over Robertson et al., and requests that the rejections be withdrawn.

SUMMARY

In consideration of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

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